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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girton	760-35 CIP	6660

7590

10/08/2003

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,521

Applicant(s)

GIRTON ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 11-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 17, 2003 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1-3 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 3 recite, "said discrete domains are extracted". It is unclear how a discrete domain, being an area in space, may be extracted. For reasons of clarity, it is suggested to change the above limitation to recite --said extractable polymeric material is extracted--. Claims 2 and 21 depend upon claims 1 and 3 and inherit all problems with the claims.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Landi (USPN 5,141,522, cited by applicant in IDS). Landi discloses a medical device, specifically a vascular graft (col.1, lines 37-41), comprising a tubular extrudate (col.1, lines 55-58) comprising an interpenetrating polymer network (col.1, lines 11-22) comprising a PTFE matrix (col.1, lines 54-55) having distributed therein discrete domains of an extractable polymeric material (col.3, lines 46-50, 64-66), wherein upon exposure to a dissolving medium or degradation temperature, the polymer is extracted from the matrix to create pores in the tubular extrudate (col.1, lines 26-29; col.3, lines 46-54).

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Zilla et al. (USPN 6,540,780 B1, cited in previous office action). Zilla discloses a medical device, specifically a vascular graft (col.1, line 12; col.2, lines 61-62) comprising a tubular extrudate (col.7, lines 46-50) comprising an interpenetrating polymer network (network being the polyurethane and PTFE interpenetrating each other) comprising a PTFE matrix (PTFE fibers form a matrix and graft material interpenetrates the matrix, col.4, lines 1-8, or material, col.10, lines 10-11) having distributed therein discrete domains of an extractable polymeric material (col.3, lines 46-49; col.4, lines 55-67), wherein upon exposure to a dissolving medium or

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degradation temperature, the polymer is extracted from the matrix to create pores in the tubular extrudate (col.6, lines 61-67).

Claims 1, 3, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell (USPN 4,764,560). Mitchell discloses a medical device, specifically a vascular graft (col.1, lines 60-62; col.3, lines 35-38) comprising a tubular extrudate (col.5, lines 65-67; col.6, lines 45-53; Table 3, it is also noted to the applicant that in both processes disclosed by Mitchell, extruding takes place, stretching occurs in only one of the processes, however whether the stretching occurs in addition to the extrusion is irrelevant since the claims do not prohibit stretching, they *comprise extruding*, which may also comprise stretching) comprising an interpenetrating polymer network (col.1, lines 11-13, 63-66) comprising a PTFE matrix (col.1, line 12) having distributed therein discrete domains of an extractable polymeric material (polymer is capable of being extracted, Table 5, therefore it is extractable), wherein upon exposure to a dissolving medium or degradation temperature, the polymer is extracted from the matrix (Table 5; col.10, lines 52-63; it is noted to the applicant that extraction and how it is completed is a method step, because this is a product claim, how the product is made is irrelevant, but what is important is the final product and the final product of Mitchell is the same as claimed) to create pores in the tubular extrudate (extraction of the polymer will create pores). Mitchell discloses the extractable polymer to comprise silicone (col.10, lines 57-59).

Claims 1, 3, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk (USPN 4,657,544, cited by applicant in IDS). Pinchuk discloses a medical device, specifically a vascular graft (10, fig.1) comprising a tubular extrudate (col.2, lines 59-61) comprising an interpenetrating polymer network (col.4, lines 5-8) comprising a PTFE matrix (col.4, line 8)

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having distributed therein discrete domains of an extractable polymeric material (silicone is *extractable*), wherein upon exposure to a dissolving medium or degradation temperature, discrete domains (as claimed) are extracted (domains are extracted, where the salt was located, col.4, lines 48-50) from the matrix to create pores in the tubular extrudate (col.4, lines 48-51; fig.3). It is noted to the applicant that extraction and method of doing so is a method step and since this is a product claim, the only concern is the end product. Pinchuk's end product comprises PTFE and pores, which is the same end product as claimed. Pinchuk discloses the extractable polymer to comprise silicone (col.4, line 8, although the silicone is not disclosed by Pinchuk to be extracted, silicone is still *extractable*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zilla et al. (USPN 6,540,780 B1) in view of Dereume et al. (USPN 5,639,278, cited in previous office action). Zilla discloses a medical device (pg.4, lines 12-13) comprising a tubular extrudate, commonly known as a graft (pg.11, lines 1-5) comprising an IPN, which comprises a PTFE matrix (pg.5, lines 15-17) having domains of an extractable polymeric material (pg.4, lines 3-4). Zilla does not teach however, a stent combined with a graft. Dereume teaches combining an axially positioned stent (22) combined with a graft (23 or 24), in order to provide increased support by the stent, enhanced tissue ingrowth by the graft, and means to cover an aneurysm in an artery or vein

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(col.2, line 64-col.3, line 4; col.3, lines 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's teaching of combining a stent with a graft, with Mitchell's type of extruded graft made of porous PTFE, in order to provide an endoprosthesis that supports an artery or vein, covers an aneurysm, enhances tissue ingrowth, etc. enhancing the overall biocompatibility of the prosthesis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller



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